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APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY. DOCKET NO.

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EXAMINER JFF-048405

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HM12/0816

ART UNIT PAPER NUMBER  
BUCKER, S 8

DATE MAILED:

08/16/00

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on 8/16/99

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 3, 5-7, & 9-12 is/are pending in the application.  
Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
☒ Claim(s) 3, 6-7 & 9-12 is/are allowed.  
☒ Claim(s) 5 is/are rejected.  
☐ Claim(s) \_\_\_\_\_ is/are objected to.  
☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.  
☐ The specification is objected to by the Examiner.  
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been  
☐ received.  
☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892  
☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_  
☐ Interview Summary, PTO-413  
☐ Notice of Draftsperson's Patent Drawing Review, PTO-948  
☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

Serial Number: 09/036,614

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Art Unit: 1645

### **Part III DETAILED ACTION**

1. Applicant's election with traverse of Group II in Paper No. 5 is acknowledged. The traversal is on the ground(s) that the invention encompassed by the claims of Group II could be examined at the same time as the invention encompassed by the claims of Group VII because the searches would substantially overlap. This is not found persuasive because art concerning the novelty of the polynucleotides does not need to address multiple uses of the polynucleotides such as their uses as probes, for expression of the protein, for gene therapy, or for antisense technology. Therefore, art drawn to the cloning or isolation of the polynucleotides in and of themselves can be substantially different from art drawn to various uses, and would not substantially overlap, thereby maintaining a search burden.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 1-2 and 13-21 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention, the requirement having been traversed in Paper No. 5.

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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4. Claims 3-12 are rejected under 35 U.S.C. 102(b) as being anticipated by Cabeza-Arvelaiz et al. ("Cabeza-Arvelaiz"). Cabeza-Arvelaiz disclose a KLC polynucleotide and polypeptide, vectors, and host cells (abstract, pages 882-883, and Figures 1-2). which meet the limitations of the claims because the claims comprise and encompass fragments of KILCH which can be found in the KLC of the prior art of Cabeza-Arvelaiz. Because of these sequence identities, the KLC of Cabeza-Arvelaiz would also hybridize to the instant invention, given that no specific conditions for hybridization are recited in order to exclude KLC.

5. Claims 4-6 and 8-9 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 4 and 8 recite a percentage of polynucleotide sequence identity, but the specification does not set forth the definitive algorithm by which this can be calculated. The specification does not describe how many and what penalties gaps are given, how long the gaps may be, whether substitutions for encoded conservative amino acids are treated differently than other substitutions, how are additions treated between sequences of unequal length, how non-coding regions are to be compared for claim 4, etc. The variables and parameters by which any algorithm can be used to calculate sequence identity are not set a constant value in such clear and concise terms in the disclosure as to give the claims metes and bounds which are definite.

Claim 5 does not set forth the specific hybridization conditions used, and several are given in the disclosure, so the claim is vague and indefinite because the artisan cannot determine from

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the claim if low, medium, or high stringent conditions are being used to set the metes and bounds. Very low stringent conditions would encompass every polynucleotide, while very high stringent conditions would just encompass SEQ ID NO:2.

Claims 6 and 9 are indefinite because they do not recite if the sequence is fully or partially complementary to the reference sequence.

6. Claim 3 (and therefore dependent claims 4-6 and 10-12) are objected to for being dependent on non-elected independent claim 1.

7. No claim is allowed.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stephen Gucker whose telephone number is (703) 308-6571. The examiner can normally be reached on Monday to Thursday from 0730 to 1800. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D., can be reached on (703) 308-3995. The fax phone number for this Group is currently (703) 308-4242, but Applicant should confirm this by phoning the Examiner before faxing.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

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Stephen Gucker

May 10, 1999